Minos Medical
15560-C Rockfield Boulevard • Irvine, CA 92618
Phone: 949-215-1835 Fax: 949-625-8625

K080550

5 510(k) Summary

JUN 10 2008

Submitter:	Minos Medical 15560-C Rockfield Boulevard Irvine, CA 928618
Contact Person:	Tom Colonna, Director of Quality
Date Prepared:	February 27, 2008
Trade name:	Megachannel Endoscopic Overtube
Classification Name:	Endoscope and Accessories (21 CFR 876.1500)
Predicate Devices:	US Endoscopy Guardus Overtube (K040836) Spirus Medical Endo-Ease Overtube (K0520840
Device Description:	The Megachannel Endoscopic Overtube is a disposable flexible PVC tube that is to be used with an endoscope. The overtube includes a proximal handle with insufflation sealing cap that accommodates a standard 12.8 mm diameter colonoscope. A removable introducer plug is attached to the distal tip to facilitate the introduction of the overtube through the gastrointestinal tract.
Intended Use:	To be used with endoscopes as a channel for multiple insertions of the endoscope into the lower gastrointestinal tract.
Comparative Analysis:	The Megachannel Endoscopic Overtube has been demonstrated to be as safe and effective as the predicate devices for its intended use.
Functional/Safety Testing:	The Megachannel Endoscopic Overtube has successfully undergone functional testing. These products have been shown to be equivalent to the predicate devices.
Conclusion:	The Megachannel Endoscopic Overtube is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 10 2008

Mr. Tom Colonna
Director of Quality
Minos Medical
15560 –C Rockfield Blvd.
IRVINE CA 92618

Re: K080550
Trade/Device Name: Megachannel Endoscopic Overtube
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODB
Dated: May 2, 2008
Received: May 5, 2008

Dear Mr. Colonna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K080550

Minos Medical
15560-C Rockfield Boulevard • Irvine, CA 92618
Phone: 949-215-1835 Fax: 949-625-8625

4 Indications for Use Statement

510(k) Number (if known): K080550

Device Name: Megachannel Endoscopic Overtube

Indications for Use:

The Megachannel Endoscopic Overtube is indicated for use in conjunction with an endoscope for tissue or foreign body manipulations and/or where multiple removal and reinsertions of the endoscope are required.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K080550

Page 1 of _1_